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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,295	09/17/2003	Peter N. Mascia	11696-047001	8833

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EXAMINER	
FOX, DAVID T	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 06/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/667,295	MASCIA, PETER N.	
	Examiner	Art Unit	
	David T. Fox	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-58* is/are pending in the application.

4a) Of the above claim(s) *37-49* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-36 and 50-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/7/04 & 3/16/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicant's election without traverse of Group I in the reply filed on 16 March 2006 is acknowledged.

Claims 1-36 and 50-58 are examined in the Office action that follows. Claims 37-49, drawn to a non-elected invention, are hereby WITHDRAWN.

The effective filing date for the instantly claimed invention is 17 September 2002, the filing date of the provisional application which discloses all aspects of the instantly claimed invention.

Claims 1-36 and 50-58 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-26 of copending Application No. 10/873,679. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one of ordinary skill in the art to utilize the method for plant transformation with a transcription activator-encoding sequence, a sequence encoding a protein of interest, and a sequence conferring seed sterility, wherein the latter two sequences are under the control of promoters with transcription activator recognition sequences; and the resultant plants, as claimed in the copending application; to obtain the instantly claimed method for plant transformation with a transcription activator-encoding sequence, a sequence encoding a protein of interest, and a sequence conferring seed sterility, wherein the latter two sequences are under the control of promoters with transcription activator recognition sequences; and the resultant plants, as instantly claimed. The use of available means of male sterility to control

pollination would have been the optimization of process parameters. The claims are coextensive.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-36 and 50-58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to methods for plant transformation with any transcription activator-encoding sequence and with promoters comprising any transcription activator recognition sites of any sequence, and the resultant transformed plants. In contrast, the specification only provides guidance for plant transformation with promoters comprising the yeast Hap1 transcription activator recognition sequence, and with a sequence encoding a chimeric transcription activator protein comprising a yeast Hap1 DNA binding domain and a herpes simplex virus VP16 transcription activator domain. No guidance is presented for the isolation or characterization of any other transcription activator-encoding sequences or any other transcription activator recognition sequences, or plants transformed therewith.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id. Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." Id.

Finally, the court held:

> A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. Id.

See also MPEP Section 2163, page 174 of Chapter 2100 of the August 2005 version, column 1, bottom paragraph, where it is taught that

> [T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

See also Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene (which includes a promoter) is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus of sequences as broadly claimed. Given the lack of written description of the claimed genus of sequences, any method of using them, such as transforming plant cells and plants therewith, and the resultant products including the claimed transformed plant cells and plants containing the genus of sequences, would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing. See the Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111.

Claims 1-36 and 50-58 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to plant transformation with promoters comprising the yeast Hap1 transcription activator recognition sequence, and with a sequence encoding a chimeric transcription activator protein comprising a yeast Hap1 DNA binding domain and a herpes simplex virus VP16 transcription activator domain; does not reasonably provide enablement for claims broadly drawn to methods for plant transformation with any transcription activator-encoding sequence and with promoters comprising any transcription activator recognition sites of any sequence, and the resultant transformed plants. The specification does not enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn to methods for plant transformation with any transcription activator-encoding sequence and with promoters comprising any transcription activator recognition sites of any sequence, and the resultant transformed plants. In contrast, the specification only provides guidance for plant transformation with promoters comprising the yeast Hap1 transcription activator recognition sequence, and with a sequence encoding a chimeric transcription activator protein comprising a yeast Hap1 DNA binding domain and a herpes simplex virus VP16 transcription activator domain. No guidance is presented for the isolation or evaluation of any other transcription activator-encoding sequences or any other transcription activator recognition sequences, or plants transformed therewith.

Gene modulation in transgenic plants or other eukaryotes via heterologous transcription activators is unpredictable. Lloyd et al teach that a chimeric transcription activator comprising a maize transcription activator and an estrogen receptor transcription activator resulted in "substantial background expression", i.e. this chimeric transcription activator was not useful in transgenic plants to produce tightly controlled gene expression (see, e.g., page 436, column 2, bottom paragraph). Lloyd et al also teach that the transient activation of gene expression by a monomeric glucocorticoid receptor transcription activator was not predictive of transcription activator function in a whole plant (see, e.g., page 439, column 1, bottom paragraph).

Schena et al teach that the monomeric yeast GAL4 transcription activator was not functional in plant cells, and that mammalian glucocorticoid receptor transcription activators function most naturally in transformed plants and fruitfly, but not in yeast (see, e.g., paragraph bridging pages 10424 and 10425).

Given the claim breadth, unpredictability and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to isolate and evaluate a multitude of transcription activator-encoding sequences and transcription activator recognition sequences for their ability to function in transformed plants to tightly control heterologous gene expression for the production of fully sterile plants.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 50-51, 53-54 and 56-58 are rejected under 35 U.S.C. 102(e) as being anticipated by Crossland et al (US 6,362,394 filed 17 August 1999).

The claims are broadly drawn to transgenic plants comprising a first transcription activator recognition sequence, promoter, and transcribable sequence including a protein-encoding sequence; and a second transcription

activator recognition sequence, promoter, and transcribable sequence causing seed infertility; wherein the plants are nuclear male sterile and may be monocots or dicots.

Crossland et al teach transgenic plants which comprise a first construct comprising a first GAL4 transcription activator recognition sequence, anther-specific promoter, and barnase protein-encoding sequence; and a second construct comprising a second GAL4 transcription activator recognition sequence, pistil-specific promoter, and barnase protein-encoding sequence which is capable of conferring seed sterility when expressed specifically in seeds; wherein the first construct confers nuclear and genetic male sterility to the plant; and wherein the plant was obtained by crossing parent plants which each contained a single construct; wherein monocotyledonous maize or dicotyledonous Arabidopsis plants may be obtained (see, e.g., Figures 1-3; column 4, lines 53-65; column 8, lines 49-63; column 9, lines 8-20; column 10, lines 24-32; column 11, lines 3-8; column 12, lines 11-67; column 14, lines 34-58; column 15, lines 1-51; column 16, lines 13-67; column 17, lines 1-21; column 18, lines 42-67; column 19, lines 1-5 and 28-39; column 21, line 15 through column 29, line 52; claims 1-2, 4-15, 17-19 and 23-28).

Claims 50-51, 53-54 and 57-58 are rejected under 35 U.S.C. 102(b) as being anticipated by Goff et al (US 6,147,282).

The claims are broadly drawn to transgenic plants comprising a first transcription activator recognition sequence, promoter, and transcribable sequence including a protein-encoding sequence; and a second transcription

activator recognition sequence, promoter, and transcribable sequence causing seed infertility; wherein the plants are nuclear male sterile and may be monocots.

Goff et al teach transgenic plants which comprise a first construct comprising a first GAL4 transcription activator recognition sequence, anther-specific promoter, and barnase protein-encoding sequence; and a second construct comprising a second GAL4 transcription activator recognition sequence, pistil-specific promoter, and barnase protein-encoding sequence which is capable of conferring seed sterility when expressed specifically in seeds; wherein the first construct confers nuclear and genetic male sterility to the plant; and wherein the plant was obtained by crossing parent plants which each contained a single construct; wherein monocotyledonous maize plants may be obtained (see, e.g., Figures 1-3; column 1, lines 19-28; column 2, lines 21-24 and 38-67; column 3, lines 6-60; column 4, lines 3-8 and 50-58; column 5, lines 14-28 and 52-67; column 6, lines 1-19 and 55-67; column 7, lines 9-20; column 8, lines 45-67; column 9, lines 16-33 and 55-67; column 10, lines 1-12 and 50-67; column 11, lines 1-28; column 14, lines 62-67; column 15; column 16, lines 12-59; column 17, lines 27-58; column 18, line 9 through column 24, line 40; claims 1-5 and 8-32).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-18, 21-36 and 50-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over each of Crossland et al (US 6,362,394 filed 17 August 1999) and Goff et al (US 6,147,282), in view of Harada et al (US 6,781,035 filed 01 March 2000).

The claims are drawn to a method for crossing a first and second plant to produce infertile seed, wherein the first plant is male-sterile and is transformed with a first construct comprising a first transcription activator recognition sequence, promoter, and coding sequence optionally encoding a peptide of interest, and a second construct comprising a second transcription activator recognition sequence, promoter, and coding sequence conferring seed sterility; wherein the second plant comprises a construct encoding a transcription activator. The claims are also drawn to the use of different transcription activator recognition sequences, the use of chemically inducible promoters for the transcription activator coding sequence, transformed monocotyledonous or dicotyledonous plants, the use of the maize ubiquitin promoter to drive expression of the transcription activator protein, the use of cytoplasmically male sterile plants as one of the parents, the use of the Arabidopsis LEC1 promoter as the seed-specific promoter for the transcription activator coding sequence, and the use of the LEC1 polypeptide-coding sequence to confer seed sterility.

The teachings of each of Crossland et al and Goff et al have been summarized above. Each reference also teaches the advantages of male sterility and female sterility for controlled pollination of desired genotypes, to avoid self-pollination, and suggests the obtention of plants which are both male

and female-sterile (see, e.g., Crossland et al, column 14, lines 34-58; column 16, lines 13-50; column 18, lines 24-41; and Goff et al, column 14, line 63 through column 15, line 14; column 16, lines 22-39; column 17, lines 27-44).

Furthermore, each of Crossland et al and Goff et al suggest the use of the maize ubiquitin promoter, chemically inducible promoters, and seed specific promoters (see, e.g., Crossland et al, column 10, lines 41-53 and 61-63; column 11, lines 3-8; and Goff et al, column 11, lines 6-11, 20-22 and 29-34).

Neither Crossland et al nor Goff et al explicitly teach the recovery of infertile seeds from the progeny of the crosses, the use of a cytoplasmically male sterile parent as one of the parents, the use of the Arabidopsis LEC1 promoter, or the use of the LEC1 coding sequence to confer seed sterility.

Harada et al teach the advantages of producing sterile seeds for a variety of agronomic crops in which the fruits are harvested for human consumption, the use of the Arabidopsis LEC1 promoter for seed-specific expression of heterologous coding sequences, the use of the LEC1 coding sequence to confer seed sterility, and the transformation of dicotyledonous Arabidopsis plants (see, e.g., column 1, lines 16-20; column 3, lines 16-24; column 4, lines 42-49; column 6, lines 32-40; column 11, lines 29-50; column 12, lines 28-37; column 18, lines 56-65; column 19, lines 9-23; column 23, lines 10-35; column 24, lines 33-53; column 30, line 20 through column 31, line 17).

It would have been obvious to one of ordinary skill in the art to utilize the method of crossing plants comprising transcription activator recognition sequences, transcription activator coding sequences, coding sequences

conferring seed sterility, and male sterile parent plants as taught by each of Crossland et al and Goff et al; and to modify that method by incorporating seed-specific promoters for the production of infertile seeds in the progeny plants, LEC1 promoters and coding sequences, and dicot transformation as taught by Harada et al; as suggested by each of the references. Choice of available cytoplasmically male sterile plants as one of the parents would have been the optimization of process parameters. Choice of known transgene to express known protein in transformed plants, wherein the plants are used as bioreactors, would have been an obvious design choice. Choice of different transactivator recognition sequences for each expression cassette, including the many transactivator recognition sequences and coding sequences taught by each of Crossland et al and Goff et al, would have also been an obvious design choice.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over each of Crossland et al (US 6,362,394 filed 17 August 1999) and Goff et al (US 6,147,282), in view of Harada et al (US 6,781,035 filed 01 March 2000) as applied to claims 1-18, 21-36 and 50-58 above; further in view of Fischer et al (US 6,906,244 effectively filed 22 June 2001), and further in view of Fischer et al (US 6,229,064, Applicant submitted).

The claim is drawn to the use of a sequence encoding a loss-of-function mutant of the FIE polypeptide to confer seed sterility.

Each of Crossland et al (US 6,362,394 filed 17 August 1999) and Goff et al (US 6,147,282), in view of Harada et al (US 6,781,035 filed 01 March 2000) teach a transcription activator-mediated method of producing infertile seeds as

discussed above, wherein a variety of seed sterility sequences are contemplated (see, e.g., Crossland et al, column 15, lines 1-51; and Goss et al, column 15, lines 15-60), but do not teach sequences encoding loss-of-function FIE mutants to confer seed sterility.

Fischer et al (US 6,906,244) teach the isolation of the FIE coding sequence and plant transformation therewith, and also teach the use of transcription activators to control gene expression (see, e.g., column 34, lines 49-67; column 35, line 30 through column 44; column 51, line 30 through column 52, line 3).

Fischer et al (US 6,229,064) teach FIE loss-of-function mutants, and suggest plant transformation therewith to confer seed sterility (see, e.g., column 1, line 60 through column 2, line 3; column 3, lines 5-10 and 52-61; column 8, lines 17-32; column 9, lines 50-56; column 10, lines 39-55; column 13, lines 33-49; column 14, line 50 through column 15, line 31; column 16, lines 64-67; column 17, line 60 through column 18, line 27; column 19, lines 23-62).

It would have been obvious to one of ordinary skill in the art to utilize the method of producing infertile seeds taught by each of Crossland et al (US 6,362,394 filed 17 August 1999) and Goff et al (US 6,147,282), in view of Harada et al (US 6,781,035 filed 01 March 2000); and to modify that method by utilizing mutant FIE coding sequences to transform plants for producing seed sterility, utilizing the methods of FIE gene isolation and plant transformation taught by Fischer et al (US 6,906,244), and the FIE mutant genes taught by Fischer et al (US 6,229,064), as suggested by Fischer et al (US 6,229,064).

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over each of Crossland et al (US 6,362,394 filed 17 August 1999) and Goff et al (US 6,147,282), in view of Harada et al (US 6,781,035 filed 01 March 2000) as applied to claims 1-18, 21-36 and 50-58 above, and further in view of Fischer et al (US 6,559,357 effectively filed 08 January 1999).

The claim is drawn to the use of a sequence encoding an ANT polypeptide to confer seed sterility.

Each of Crossland et al (US 6,362,394 filed 17 August 1999) and Goff et al (US 6,147,282), in view of Harada et al (US 6,781,035 filed 01 March 2000) teach a transcription activator-mediated method of producing infertile seeds as discussed above, wherein a variety of seed sterility sequences are contemplated (see, e.g., Crossland et al, column 15, lines 1-51; and Goss et al, column 15, lines 15-60), but do not teach sequences encoding ANT polypeptides to confer seed sterility.

Fischer et al teach plant transformation with an ANT-encoding polynucleotide for the production of sterile seeds, wherein a transcription activator-mediated method of gene expression is also taught (see, e.g., column 1, lines 22-26; column 2, lines 18-23 and 48-50; column 8, lines 4-59; column 9, lines 31-35; column 11, lines 9-18; column 15, lines 29-35; column 17, line 55 through column 18, line 57).

It would have been obvious to one of ordinary skill in the art to utilize the method of producing infertile seeds taught by each of Crossland et al (US 6,362,394 filed 17 August 1999) and Goff et al (US 6,147,282), in view of Harada

et al (US 6,781,035 filed 01 March 2000); and to modify that method by utilizing ANT coding sequences to transform plants for producing seed sterility, as suggested by Fischer et al (US 6,559,357).

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is 571-272-0795. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

May 29, 2006

DAVID T. FOX
PRIMARY PATENT EXAMINER
ART UNIT 1638